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08/877,317	06/17/97	COOK	P ISIS-2508

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JOSEPH LUCCI
WOOD COCK WASHBURN KURTZ
MACKIEWICZ AND NORRIS
ONE LIBERTY PLACE-46TH FLOOR
PHILADELPHIA PA 19103

EXAMINER

MARTINELL, J

ART UNIT

PAPER NUMBER

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UNITED STATES DEPARTMENT OF COMMERCE
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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 19

Application Number: 08/877,317
Filing Date: June 17, 1997
Appellant(s): Cook

date mailed 12.4.00

Gregory L. Hillyer
For Appellant

EXAMINER'S ANSWER

**This is in response to appellant's brief on appeal filed
September 20, 2000.**

Serial No. 08/877,317

Art Unit 1633

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(7) *Grouping of Claims*

The appellant states that the claims stand or fall together.

Serial No. 08/877,317

Art Unit 1633

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

No prior art is relied upon by the examiner in the rejection of the claims under appeal. However, one reference, Rojanasakul (Advanced Drug Delivery Reviews 18: 115-131 (1996)) was relied upon as evidence of the state of the art at the time the invention was made.

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims.

Claims 13-16, 19, 20, and 22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application does not adequately teach an effect on any organism by administration of any of the modified PNAs mentioned in the claims. Rojanasakul is cited here as evidence that antisense treatment of organisms involves several problems, among them, stability of the oligonucleotide, uptake of the oligonucleotide, and specificity of hybridization of modified oligonucleotides to their intended targets. The instant application does not address these problems in connection with the administration of an antisense agent to an organism.

Serial No. 08/877,317

Art Unit 1633

Appellant's arguments (appeal brief, pages 4-7) are not convincing. First, appellant argues that there is no legal requirement that an application provide an enabling disclosure in any particular manner. It is agreed that this is correct; however, this was not at issue in this record. Appellant goes on to state, "An enabling disclosure can be provided by the use of illustrative examples or simply by broad terminology." Again, this was not the issue since the instant application provides no working example of administration of an antisense agent to an organism. Although there is no requirement for disclosure of a working example, claims may be rejected for failing to meet the requirements of 35 U.S.C. § 112, first paragraph in certain unpredictable arts. Appellant acknowledges as much in the Brief at page 5, first full paragraph, in pointing out the burden of the USPTO to provide evidence and/or reasoning in connection with doubts about whether the disclosure would enable one of skill in the art to practice the claimed invention. Appellant then asserts that the record does not contain such evidence or reasoning. The examiner disagrees and this is the issue.

The Rojanasakul article is of record as evidence that the use of ONs (oligonucleotides) as antisense agents is and unpredictable art. Passages in the Rojanasakul article that support this notion can be found at the following locations:

- (a) in the abstract, "In this article . . . successful utilization of these compounds.",
- (b) page 118, left-hand column, lines 3-13,

Serial No. 08/877,317

Art Unit 1633

- (c) paragraph bridging pages 118-119, and
- (d) paragraph bridging pages 122-123.

Rojanasakul points out several pitfalls associated with treatment of organisms with ONs as antisense agents. Among them are: uptake of the antisense agent into cells, stability of the ONs in cells, and specificity of hybridization of the ONs once inside the cells. The instant application does not address these problems or indicate how they may be overcome in the administration of the PNA-DNA-PNA compounds mentioned in the claims. Appellant asserts that the Rojanasakul article constitutes "compelling evidence" that the state of the art at the time the application was filed was "such that an artisan could readily obtain at least some measurable test results once armed with the teachings of the present application." One cannot find this argument convincing in view of the difficulties disclosed in Rojanasakul discussed above. The passage of Rojanasakul referred to by appellant (Brief, page 6) is at best an invitation to experiment.

The instant application does not teach any more than is alluded to by Rojanasakul as being the state of the art. The following locations in the instant application are the only locations that disclose the administration of antisense agents to organisms:

- (a) Abstract (page 58),
- (b) Background (pages 2-5),

Serial No. 08/877,317

Art Unit 1633

- (c) Objects of the Invention (page 5),
- (d) Brief Description of the Invention (page 8, line 25 through page 9, line 21 and pages 22-23), and
- (e) Example 17 (pages 41-48).

These parts of the instant application describe the administration of antisense agents to organisms in only the most general terms and disclose no particular results. Appellant has not pointed to any part of the instant application that might contain a disclosure that could rebut the reasoning advanced by the examiner in combination with the article by Rojanasakul nor has appellant established the level of skill in the art to be such that one of skill in the art could practice the claimed invention as disclosed.

For the above reasons, it is believed that the rejection should be sustained.

Respectfully submitted,

JM
December 1, 2000

R. W. Hill
Conferee
Quality Assurance Specialist
Technology Center 1600

J. Martinell
JAMES MARTINELL, Ph.D.
SENIOR LEVEL EXAMINER

e877317f.wpd

DRC conferee
DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

PAGE 6